

Amendments to the Claims

1-7. (Cancelled)

8. (Currently Amended) A substantially purified nucleic acid molecule that encodes a soybean protein or fragment of a soybean protein comprising a nucleic acid sequence ~~selected from the group consisting of SEQ ID NO: 5278 through SEQ ID NO: 45553~~ or its complement.

9. (New) The substantially purified nucleic acid molecule of claim 8, wherein said nucleic acid molecule consists of a nucleic acid sequence of SEQ ID NO: 5278 or its complement.

10. (New) The substantially purified nucleic acid molecule of claim 8, wherein said substantially purified nucleic acid molecule comprises a region having a single nucleotide polymorphism.

11. (New) A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5278 or its complement.

12. (New) The substantially purified nucleic acid molecule of claim 11, wherein said nucleic acid molecule consists of a nucleic acid sequence of SEQ ID NO: 5278 or its complement.

13. (New) The substantially purified nucleic acid molecule of claim 11, wherein said substantially purified nucleic acid molecule comprises a region having a single nucleotide polymorphism.

I. Support for Amendments

Claim 8 has been amended. New claims 9-13 have been added. Upon entry of the foregoing amendments, claims 8-13 are pending in the application. Support for these amendments may be found throughout the specification and in the original claims, for example at page 16, line 20 through page 17, lines 10; page 18, lines 1 through page 20, lines 8; page 23, line 18 through page 25, line 4; page 31, line 24 through page 32, line 7; and page 34, lines 1-4. No new matter enters by these amendments.

II. The Restriction Requirement

Applicants thank the Examiner for noting that pursuant to the Amendment filed September 24, 2001, claims 1-7 were cancelled without prejudice to or disclaimer of the underlying subject matter, new claim 8 was submitted, and that “both the restriction requirement, and applicant’s election of Group I are moot.” Office Action at page 2.

Applicants also acknowledge the finality of the election requirement to a single nucleotide sequence, but maintain their traversal. Applicants respectfully disagree that the polynucleotide sequences of the instant application would be considered of the complexity that merits restriction to a single sequence in contradiction to the expressed USPTO policy of examining ten sequences, as set forth in the Manual of Patent Examining Procedure. (*See* MPEP, 8th ed., August 2001, Section 803.04, page 800-10.) However, in order to facilitate prosecution Applicants have removed non-elected sequences from the claims.

III. Sequence Listing

Applicants thank the Examiner for noting that the computer-readable sequence listing was approved by STIC for matters of form. Office Action at page 3.

IV. Objection to the Specification

The Examiner has objected to the specification on the grounds that it contains an embedded hyperlink and/or other form of browser-executable code. Office Action at page 3. In order to facilitate prosecution, the specification has been amended to remove embedded hyperlinks and/or other forms of browser-executable code. No new matter enters by these amendments. The URL addresses themselves contained throughout the specification do not constitute browser-executable code in the absence of embedded hyperlinks and/or other forms of browser-executable code. The specification as amended does not contravene stated PTO policy of prohibiting live web links to other web pages, which might be commercial. (MPEP, § 608.01 (d).)

V. Rejection under 35 U.S.C. § 101 (Utility)

Claim 8 stands rejected under 35 U.S.C. § 101, first paragraph, as allegedly lacking a “specific and/or substantial” asserted utility or a well-established utility. The Office alleges that “[t]he claimed subject matter is not supported by a specific, substantial and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter,” and that “further characterization of the claimed subject matter would be required to identify or reasonably confirm a “real world” use.” Office Action at page 3. The Office also asserts that “[n]either the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid compounds such that another non-asserted utility would be well established for the compounds.” Office Action at page 5. Applicants respectfully disagree.

Applicants respectfully submit that the application of the Interim Guidelines ignores the presently disclosed utilities and contravenes well-established doctrines of utility developed in the courts. It is well-established law that “when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown.” *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983).

Applicants respectfully submit that the specification describes multiple objectives and utilities that are met by the present invention. For example, the claimed nucleic acid molecules are useful in determining the presence of polymorphisms, isolating specific promoter sequences, and obtaining nucleic acid homologues. (*see, e.g.*, specification, beginning at page 34, under heading "Uses of the Agents of the Invention").

The Office alleges that neither the specification nor any art of record discloses or suggests any property or activity for the nucleic acid molecules. Office Action at page 5. Applicants respectfully disagree. For example, Applicants note that SEQ ID NO: 5278 is derived from library SOYMON031. *See, e.g.*, specification at page 86, lines 13-14. Applicants further direct the Examiner's attention to the paragraph in the specification at page 31, line 24 through page 32, line 7, which recites that library SOYMON031 are from carpel and stamens. In addition, library SOYMON31 is derived from a soybean that has disease resistance to brown stem rot (*Phialophora gregata*) and *Phytophthora* root rot (*Phytophthora sojae*). *See, e.g.*, specification at page 34, lines 1-4. As such, Applicants disagree that the specification fails to disclose or suggest any property or activity for the nucleic acid compounds.

Applicants further note that it is standard practice to use nucleic acids of known sequence (*e.g.*, SEQ ID NO: 5278) to perform gene expression analysis using methods such as microarray technology. Knowing that an RNA corresponding to the claimed nucleic acid molecule is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect and compare expression changes in tissue samples taken from organisms grown under different conditions, *e.g.*, drought stress, cold stress, exposure to pathogens, or exposure to chemical compounds. SEQ ID NO: 5278 might be differentially expressed, for example, under one or more growth conditions that tend to induce expression changes in genes involved in plant growth (*e.g.*, growth in the presence of plant hormones), or in genes involved in growth resistance to brown stem rot (*Phialophora gregata*) or *Phytophthora* root rot (*Phytophthora sojae*). *See, e.g.*, page 31, line 24 through page 32, line 7; and page 34, lines 1-4.

Microarrays allow rapid, simultaneous expression analysis of thousands of sequences, and thus, informative *patterns* of expression are derived from the microarray expression data. A microarray experiment using SEQ ID NO: 5278 to study gene expression relating to plant growth (*e.g.*, growth in the presence of plant hormones), or gene expression relating to resistance to *Phialophora gregata* or *Phytophthora sojae* is **not** equivalent to studying the properties of the claimed subject matter itself. Applicants respectfully submit that expression analysis is a use of SEQ ID NO: 5278 in a real world context. Applicants further submit that the specification teaches one of skill in the art how to use SEQ ID NO: 5278 for this purpose. *See, e.g.*, specification at page 54, line 1 through page 56, line 1 (describing use of SEQ ID NO: 5278 for microarray analysis of gene expression profiles).

Many of the uses described in the specification are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner attempts to undermine the existing utilities by stating that they are “generally applicable to broad classes of this subject matter,” Office Action at page 4. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) (“An invention need not be the best or the only way to accomplish a certain result...”).

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading “into the patent laws limitations and conditions which the legislature has not expressed,” a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a *unique* subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner states that the credibility of the presently asserted utilities has not been assessed. Office Action at page 5. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined “by reference to, and a factual analysis of, the disclosure of the application.” *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner “has the initial burden of challenging a presumptively correct assertion of utility in the disclosure.” *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The

Examiner “must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability.” *In re Gaubert*, 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 2107.01 (“Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...”). Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner’s admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. An invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under 35 U.S.C. § 101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

VI. Rejection under 35 U.S.C. § 112, First Paragraph (Enablement)

Claim 8 stands rejected under 35 U.S.C. § 112, first paragraph, on the grounds that, as claim 8 allegedly lacks a “specific and substantial” asserted utility or a well-established utility, one skilled in the art would therefore allegedly not know how to use the claimed invention so that it would operate as intended without undue experimentation. Office Action at page 4. Applicants respectfully traverse this rejection, and submit that this rejection has been overcome by the foregoing arguments regarding utility. Applicants therefore respectfully request reconsideration and withdrawal of the enablement rejections under 35 U.S.C. § 112, first paragraph.